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Case No. 131.02US

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Inventor(s): Singh et al.

Serial No: 10/812,619

Filed: 30 March 2004

For: Surface Receptor Comlexes as

Biomarkers

Examiner: Not Yet Assigned

Art Unit: 1641

Confirmation No. 3231

## SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450

The references cited on the accompanying PTO-1449 form(s) were cited in an International Search Report for the co-pending international patent application PCT/US2004/09717 filed 07 Jan. 2005. A copy of the International Search Report is enclosed. The references cited may be material to the examination of the above-identified application and are, therefore, submitted in compliance with the duty of disclosure defined in above-identified application and are, therefore, submitted in compliance with the duty of disclosure defined in 37 CFR 1.56 and 1.97. The Examiner is requested to make these citations of official record in this application. 2) CFR 1.30 and 1.37. The Examiner is requested to make mese changes of children record in this application (s) to the Copies of the cited references are enclosed or have been previously submitted in prior application(s) to the above application.

This Information Disclosure Statement under 37 CFR 1.56 and 1.97 is not to be construed as a representation that a search has been made, that additional information material to the examination of this application does not exist, or that any one or more of these citations constitutes prior art.

#### SUBMISSION INFORMATION

区	This Information Disclosure Statement is being submitted within three (3) months of filing or belove mailing of a first Office Action, whichever occurs last. (37 CFR 1.97(b))
	This Information Disclosure Statement is being submitted before the mailing date of either a final Office Action or a Notice of Allowance. (37 CFR 1.97(c)) Applicant elects to pay the fee set forth in 37 CFR 1.17(p) for submission of the Information Disclosure Statement under 37 CFR 1.97(c).
	This Information Disclosure Statement is being submitted after the mailing date of a final Office Action or Notice of Allowance, whichever occurs first, but before, or simultaneously with, the payment of the issue fee. (37 CFR 1.97(d)) Applicant hereby petitions for the consideration of this Information Disclosure Statement under 37 CFR 1.97(d)(ii). The petition fee under 37 CFR 1.17(i)(1) is authorized or enclosed as indicated below

#### PAYMENT OF FEES (IF ANY DUE)

FEE AUTHORIZATION. The Commissioner is hereby authorized to withdraw from Deposit 50-2266 Account

any submission fees or petition fees required for this Information Disclosure Statement.

Respectfully submitted,

Stephen C. Macevicz Registration No. 30,285

Enclosures:

1449 form(s) Copy of International Search Report

Form PTO-1449 (adapted)	Docket No. Aclara ref. 131.02US Serial No. 10/812,619
REFERENCES CITED BY APPLICANT	Chan-Hui et al  Filing Date 30 March 2004  Group 1641
Page 1 of 1	30 War Ch 200 .

			U.S. P	ATENT D	OCUMENTS	Issue/Publ. Date
Examine		Document	First Inventor	Class /Subclass	Title	(mm/dd/yyyy)
r's Initial		Number		435/69.5	Compositions and Methods for Production	12 Sept. 2002
	P1	US2002/0127654A1	Price et al		Cell Culture  Modifications of VEGF Receptor-2 Protein	07 Nov. 2002
	P2	US2002/0164641A1	McTigue et al	435.7.1	and Methods of Use	

	Date considered
1	*EXAMINER: Initial if reference considered, whether or not citation in conformance with MPEP 609; Draw line through citation if not in  *EXAMINER: Initial if reference considered, whether or not citation in conformance with MPEP 609; Draw line through citation if not in
	*EXAMINER: Initial if reference considered, whether or not catation in communication to applicant.  conformance and/or not considered. Include copy of this form with next communication to applicant.

## PATENT COOPERATION TREATY

### **PCT**

### INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

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Applicant's or agent's file reference	FOR FURTHER	Report (For	ion of Transmittal of International Search n PCT/ISA/220) as well as, where applicable,
31.02WO	ACTION  International filing date (day/m	item 5 belov orth/year)	(Earliest) Priority Date (day/month/year) 01: April 2003 (01.04.2003)
International application No. PCT/US04/09717	30 March 2004 (30.03.2004)	1	
Applicant ACLARA BIOSCIENCES, INC			
	en prepared by this International	l Searching Au	thority and is transmitted to the applicant
according to Article 16. A copy	2 cheets		
This international search report consis	TOT OF MALES	locument cited	in this report.
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6 The figure of the drawings t	o be published with the abstract is	Figure No. 1	None of the figures
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because the applican	nt failed to suggest a figure. better characterizes the invention.	•	
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Category *	Citation of documents (12 September 2002 (1	2.09.2002	J, pares	5-11, 13, 15-18
X	US 2002/0127654 A1 (PRICE et al.) 12 07 November 20 US 2002/0164641 A1 (MCTIGUE et al.) 07 November 20	02 (07.11	.2002), abstract,	8, 12, 14, 19-25
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## PATENT COOPERATION TREATY

PATENT COO	PERATION	
om the TERNATIONAL SPARCHING AUTHORITY	7.	PCT
TO: STEPHEN C. MACEVICZ ACLARA BIOSCIENCES, INC.	WR INTERNATI	ITTEN OPINION OF THE ONAL SEARCHING AUTHORITY
1288 PEAR AVENUE MOUNTAIN VIEW, CA 94043		(PCT Rule 43bis.1)
	Date of mailing	07 JAN 2005
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Applicant's or agent's file reference	(in/month/year)	(3-) (month (vear)
Interpational application No.	ing date (day/month/year)	01 April 2003 (01.04.2003)
PCT/US04/09717 International Patent Classification (IPC) or both national	classification and IPC	
International Patent Citation IPC(7): G01N 33/53 and US Cl.: 435/7.1		
Applicant		
ACLARA BIOSCIENCES, INC	lewing items:	
1. This opinion contains indications relating to the following	IOMINE 1	
Basis of the opinion		
Box No. II Priority	inion with regard to novelt	y, inventive step and industrial applicability
Box No. III Non-establishment of options and the state of	an and an	or industrial
Box No. IV Lack of unity of artement under	er Rule 43bis.1(a)(i) with	regard to novelty, inventive step or industrial such statement
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Authority other than this one to be the IPEA	ching Authority will not be	nion will be considered to be a wrinen opinion of the this does not apply where the applicant chooses an opinion of the international Bureau under Rule 66.1bis(b) as considered.
If this opinion is, as provided above, conside IPEA a written reply together, where appropriate a written reply together.	ered to be a written opinion opriate, with amendments expiration of 22 months fr	n of the IPFA, the applicant is invited to submit to the before the expiration of 3 months from the date of om the priority date, whichever expires later.
For further options, see 1 6121		_
3. For further details, see notes to Form PCT/E	1	orized officer
Name and mailing address of the ISA/ US Mail Stop PCT, Aun: ISA/US	l l	orah A Davis Feat Proctor Paralegal Specific
Mail Stop PCJ Commissioner for Patents P.O. Box 1450 Alexandris, Virginia 22313-1450 Alexandris, 205 3230	- Telep	phone No. (572) 272-0818
Facsimile No. (703) 305-3230  Form PCT/ISA/237 (cover sheet) (January 2004)	)	_
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## WRITTEN OPINION OF THE NATIONAL SEARCHING AUTHORITY

[	International application No.	
1	PCT/US04/09717	_

	WRITTEN OPINION OF AUTHORITY	PCT/US04/09/17
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or No. 1 Ba	sis of this opinion	
	o the language, this opinion has been established on the basi	of the international application in the language in which
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With regard to	o the language, this opinion has been unless otherwise indicated under this item.  The basis of a translation from	the original language into the following language,
I Was Incu,		international search (under Rules 12.3 and 25.70%)
which	inless otherwise indicated under his held.  pinlon has been established on the basis of a translation from is the language of a translation furnished for the purposes of is the language of a translation furnished.	d in the international application and necessary to the
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Form PCT/ISA/237(Box No. 1) (January 2004)

#### WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY

n	WRITTEN OPHIACITY AUT	THORITY  bis.1(a)(i) with regard to novelty, inventive step or is in the supporting such statement	ndustrial
Box No.	<ul> <li>Reasoned statement under Rule 43 l applicability; citations and explanation</li> </ul>	ions supporting such statement	
	<del></del>		YES
1. Statem		Claims 3-25	NO
	Novelty (N)	Claims 1-2	YES
		Claims 3-4, 8, 12, 14, 19-25	NONO
1	Inventive step (IS)	Claims 1-2, 5-7, 9-11, 13, 15-18	
1			YES
		Claims 1-25	NO
1	Industrial applicability (IA)	Claims NONE	
\			•

Claims 1-2 lack novelty under PCT Article 33(2) as being anticipated by Price et al US 2002/0127654. Claims 1-2 lack novely under PC1 Affice 33(2) as being anticipated by Frice et al US 2002/012/034.

Price et al teaches methods of detecting cell surface receptors that express proteins related to breast, colon and prostate cancer 2. Citations and explanations:

Claims 5-7, 9-11, 13, 15-18 lacks an inventive step under PCT Article 33(3) as being obvious over Price et al in view of McTigue et (paragraph 0031.)

McTigue et al teaches receptors such as VEGFR, PDGFR and others that serve as potential makers in the screening process for tumor suppressor drugs paragraph 0019, 0020 and 0022. It would have been obvious to modify the teachings of Prices et al to include detection of sheet receptor markers because they are instrumental in screening for any detection. tumor suppressor urugs paragraph 0013, 0020 and 0022. It would have been bovious to monthly the tea include detection of these receptor markers because they are instrumental in screening for new drugs.

Claims 1-25 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

Form PCT/ISA/237 (Box No. V) (January 2004)

#### NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

# The following examples illustrate the manner in which amendments must be explained in the accompanying

- [Where originally there were 48 claims and after amendment of some claims there are 51]:
  "Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers;
  white 30, 33 and 36 unchanged; new claims 49 to 51 added." letter: claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- 2. [Where originally there were 15 claims and after amendment of all claims there are 11]: "Claims 1 to 15 replaced by amended claims 1 to 11."
- 3. [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims; "Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
  - "Claims 1 to 0 and 14 unchanged; claims / to 13 canceded; new claims 13, 16 and 17 added; all other claims unchanged." "Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- [Where various kinds of amendments are made]:
  "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended "Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 20 and 21 added."
  claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

The amendments may be accompanied by a statement explaining the amendments and indicating any impact "Statement under Article 19(1)" (Rule 46.4) The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under that such amendments might have on the description and the drawings (which cannot be amended under that such amendments may be accompanied by a statement explaining the amendments and indicating any impact.

The statement will be published with the international application and the amended claims.

# It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

# Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International filing the amendments (and any statement) and, where required, a Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2. first Prehiminary Examining Authority a copy of such amendments (and or any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/IPEA/401).

# Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the PCT Applicant's Guide, Volume II.

Notes to Form PCT/ISA/220 (second sheet) (July 1998; reprint April 2002)